

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES

v.

KINGSLEY R. CHIN and
ADITYA HUMAD,
Defendants.

No. 1:21-cr-10256-IT

**DEFENDANTS’ OPPOSITION TO GOVERNMENT’S MOTION *IN LIMINE* TO
PRECLUDE EVIDENCE OR ARGUMENT CONCERNING LACK OF PATIENT HARM
OR ABSENCE OF MEDICALLY UNNECESSARY SERVICES**

Defendants Kingsley Chin and Aditya Humad respectfully oppose the government’s motion *in limine* that attempts to preclude the defendants from using evidence or making arguments concerning the lack of patient harm or the absence of medically unnecessary services.

Preliminary Statement

While the government may be correct that it has no burden to prove that the defendants caused harm to patients or caused medically unnecessary services, the government’s motion takes an erroneous leap concerning the scope of admissible evidence. The government argues that defendants cannot rely on circumstances surrounding the consulting program at issue, even to attack the credibility of witnesses (including doctors who may testify that they accepted bribes to use SpineFrontier products in surgeries for their patients), or to rebut accusations of a “sham” consulting program, evidence of their alleged willfulness, or efforts by the government to establish a conspiratorial intent to induce improperly referrals of business. The government misplaces reliance on case law that fails to support its overaggressive position.

At most, after the completion of the government's case-in-chief or at the charge conference, this Court will be able to address whether the government is entitled to pertinent jury instructions. For example, the government may request an instruction that it need not prove patient harm or medically unnecessary services. Or perhaps the government will be entitled to a limiting instruction that evidence of benefits to patients and improvements to the treatment of them are relevant to only the issues of credibility of witnesses, or whether the government has met its burden of proving that each defendant intentionally induced a surgeon to refer business to SpineFrontier or whether each defendant acted knowingly or willfully.

As described below, the case law on which the government relies does not, however, support a pretrial parsing apart of evidence or argument about surrounding circumstances on issues of credibility or *mens rea*. Importantly, our adversarial system allows defendants to challenge the accusations against them and, here, to demonstrate both that the consulting program was far from the "sham" that the Indictment alleges and show how the program served lawful benefits for patients. Accordingly, this Court should deny the government's motion or at least defer it until the appropriate time during the trial.

Background

Evidence at trial will show that, with respect to SpineFrontier's consulting program, each of the defendants acted in good faith, with the goal of innovation for SpineFrontier's industry-leading products which in turn would improve care for patients. Recently, as a newly-configured prosecution team has interacted with witnesses and reviewed reports of witness statements, the government has dismissed or sought dismissal of all charges against SpineFrontier and three of the substantive counts charging Dr. Chin and Mr. Humad with violations of the Anti-Kickback Statute. In doing so, the government has dropped its accusations about more than 75% of the payments that appeared in the original charges.

Nevertheless, the Indictment that the Grand Jury returned still charges that the defendants put in place and used a “sham” consulting program. Specifically, Paragraph 29 of the Indictment charges that defendants are responsible for directing bribes to surgeons “pursuant to a sham consulting program.” Paragraph 30 also refers to “SPINEFRONTIER’s sham consulting program.” In Paragraph 32, the Indictment alleges that Chin and Humad “designed” the consulting program for the purpose of making “bribes” to surgeons. In Paragraph 37(j), the Indictment alleges the creation of records and documents, “including purportedly legitimate contracts, designed to make the sham consulting program appear legitimate.” The Indictment also impugns the entirety of the consulting program by alleging that Impartial Medical Experts, LLC, the entity through which *all* consulting payments were made after a particular period, not just payments to alleged co-conspirators, “*purported* to manage the process pursuant to which SPINEFRONTIER’s surgeons submitted hours and received payments from or on behalf of SPINEFRONTIER for *purported* consulting.” (Indictment ¶ 4 (emphases added).) Having now gutted its own case by dismissing three of seven counts, and the only corporate-entity defendant, the government now suggests that defendants cannot rebut these accusations or show that the form of contract used in the program supported proper consulting work.

In the context of an allegedly “sham” consulting program, the Indictment places at issue whether each defendant interacted with SpineFrontier’s consulting program with a bad purpose to violate the law, a proper purpose to innovate for the benefit of patients, or some other innocent purpose. The pertinent provisions of the Anti-Kickback Statute invoked in the remaining three substantive counts in the Indictment provide:

Whoever **knowingly and willfully** offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person **to induce such person—**

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a–7b(b)(2) (emphases added). The Indictment also charges a conspiracy, placing at issue whether the defendants shared a common unlawful purpose and corrupt intent to conspire through a “sham” consulting program, in violation of 18 U.S.C. § 371.

Despite these issues for trial, the government seeks broad preclusion of evidence and argument, including prohibitions that could limit the jury’s ability to consider whether the consulting program existed or continued because of its positive impact on patients and the defendants’ intent to improve medical care. To be clear, the defendants do not seek to conduct a mini-trial over harm or benefits to patients, or whether any physicians could disagree about the best form of treatment. Neither the government nor either of the defendants has identified a retained expert witness to opine about the quality or consequences of medical care or necessity. Nevertheless, a jury should be able to assess the credibility of any government witnesses who criticize the consulting program as a sham or the like, or whether each of the defendants lacked criminal culpability and made payments for a purpose other than for inducing purchases, at least in part because physicians chose SpineFrontier’s products as the best choice for their patients.

Discussion

The Defendants are Entitled to Attack the Credibility of Government Witnesses, and to Rebut the Government’s Theories of Willfulness and Efforts to Prove Payments for Inducing Purchases, Including Through References to Reasons to Believe in Positive Impacts on and Proper Care for Patients.

The government seeks to cripple the defendants’ ability to rebut express accusations of a “sham” consulting program that appears in the Indictment, and to preclude an attack on the credibility of government witnesses or otherwise challenge any proof of the defendants’ alleged

criminal intent. Specifically, the government attempts in this motion to block evidence and argument about positive aspects of the consulting program that naturally contributed to a belief in its propriety. Proving a violation of the Anti-Kickback Statute requires proof beyond a reasonable doubt that defendants acted knowingly and willfully. *See* 42 U.S.C. § 1320a-7b(b)(2). Willfulness is to be determined based on “all the surrounding circumstances.” *Rutkin v. United States*, 343 U.S. 130, 135 (1952); *see United States v. Mena*, 933 F.2d 19, 25 n.5 (1st Cir. 1991) (allowing evidence of after-the-fact acts as having “obvious evidentiary significance in establishing what happened during” the event at issue because a defendant’s intent can be inferred “in light of all the surrounding circumstances”) (citation omitted); *United States v. Johnstone*, 107 F.3d 200, 209 (3d Cir. 1997) (“Knowledge and intent may be inferred from all the surrounding circumstances ... [including] all the natural and probable consequences of an act knowingly done.”).

In the context of the Anti-Kickback Statute specifically, the *mens rea* element requires proof that the defendants knew that the specific actions they took were illegal. *See United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 157 (2d Cir. 2024), *cert. denied*, No. 23-1293, 2024 WL 4426646 (U.S. Oct. 7, 2024) (“[T]he defendant must act with knowledge that his conduct was unlawful.”) (internal quotation marks omitted); *Pfizer, Inc. v. United States*, 42 F.4th 67, 77 (2d Cir. 2022); *United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000); *United States ex rel. Langer v. Zimmer Biomet Holdings, Inc.*, 743 F. Supp. 3d 282, 292 (D. Mass. 2024) (“To establish a knowing and willful violation, Relator’s complaint must allege that Zimmer acted with knowledge that its conduct was unlawful.”).

The Indictment alleges that the consulting program was a “sham” and “designed” only for bribes. These allegations relate to the *mens rea* elements of willfulness and conspiratorial intent. As a fundamental matter, defendants are entitled to rebut these accusations and anticipated

testimony by government witnesses, including on *mens rea* issues. Potential defense strategies focus on knowledge and intent, including through a look at the limited amount of consulting payments at issue compared to the value of benefits and improvements in the innovation of products and patient care, which a jury could find constituted the real purpose of the payments. Given issues of witness credibility and the importance of *mens rea* requirements for the crimes charged, the defendants should be permitted to address these surrounding circumstances.

Furthermore, the language in the Indictment and reports produced by the government suggest that one or more of its witnesses may testify that the consulting program was a “sham” or the like and that it incentivized a surgeon to conduct unnecessary procedures or use more products for monetary reasons. Such information may be relevant only to the extent sufficiently linked to a defendant’s understanding about a bad purpose for the consulting agreement. To the extent, however, that either of the defendants had reasons to believe instead that the consulting program developed innovation and helped patients, such information tends to show a lack of *mens rea*.

The cases on which the government relies do not support the broad preclusion ruling that it seeks. Most of the cases merely stand for the proposition that the government need not prove harm to patients or a lack of necessity for medical services as essential elements of the charged offenses. In the first case on which the government relies, *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20 (1st Cir. 1989), the court addressed a Medicare fraud provision and assessed whether a jury instruction that expressly required the government to prove “corrupt intent” sufficed without giving an instruction, which the defense requested, stating that the reasonableness of payments could provide a defense. Contrary to the government’s approach in the present motion, the First Circuit ruled that “the circumstances surrounding the conduct and statements were relevant.” *Id.* at 33. As in *Bay State Ambulance*, *mens rea* for a specific intent

offense is at issue here. There the court reasoned that the jury found the defendant “not guilty on all but one check payment,” which reflected that it “could have believed that the check payments were compensation for work done with only an incidental improper purpose” and therefore acquitted on those charges, while finding the delivery of two cars to have an improper purpose. *Id.* at 30. In other words, by focusing on how surrounding circumstances reflected genuine value, the *Bay State Ambulance* decision refutes, rather than supports, the government’s present position.

Other case law on which the government relies is equally unhelpful for its position. Oddly, the government next cites to this Court’s decision in a civil case, *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-CV-10601-IT, 2018 WL 1996829 (D. Mass. Apr. 27, 2018). In *Biogen Idec*, this Court addressed a motion to dismiss under Fed. R. Civ. P. 12(b)(6) and found that a relator need not allege as a specific *quid pro quo* that a payee carried through with “changed prescribing habits” in exchange for a payment. *Id.* at *3. Nothing in this Court’s *Biogen Idec* decision remotely addressed the scope of evidence with which a defendant can attack express accusations or the credibility of witnesses, or how a defendant can rebut proof of *mens rea* or conspiratorial intent to induce referrals. Indeed, exposure to good results from consulting payments would be a fact from which a jury could infer that a defendant lacked both the *mens rea* that the government must establish as criminal and the conspiratorial intent to commit an unlawful act.

The government relies on another civil case, *United States ex rel. Witkin v. Medtronic, Inc.*, No. 1:11-CV-10790-IT, 2024 WL 1892405, at *15 (D. Mass. Mar. 31, 2024), which arose in the context of summary judgment standards. In *Medtronic*, this Court explained the right of even civil defendants to present expert testimony and surrounding circumstances to impeach the credibility of witnesses and establish the fair value of payments, which would also bear on willfulness and conspiratorial intent issues here:

To the extent Medtronic attempts to question McNamara's credibility generally and offers an expert who reaches a different conclusion, that is a determination for the trier of fact, not the court. "So long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities." *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (internal quotation marks and citation omitted). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993)). Thus, because resolution of this fair-market-value dispute would require the court to choose between the well-grounded opinions of competing experts, summary judgment is inappropriate on the issue.

Id. at *15.¹

The government also relies on *Pfizer, Inc. v. United States Dep't of Health & Hum. Servs.*, 42 F.4th 67 (2d Cir. 2022), in which *Pfizer* challenged an advisory opinion issued by the Department of Health and Human Services on December 9, 2019, prior to the deregulatory impact of *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024). To be clear, the advisory opinion from HHS post-dates the Indictment in this case and has no application or evidentiary value here. As in the *Biogen Idec* case, nothing in *Pfizer* remotely addresses the admissibility of evidence concerning surrounding circumstances as part of defending against criminal charges that require the proof of heightened *mens rea* and conspiratorial intent to achieve an unlawful purpose. Indeed, the *Pfizer* decision reaffirms that substantive offenses under the Anti-Kickback Statute contain essential elements of specific intent for a *quid pro quo*. *Pfizer, Inc.*, 42 F.4th at 72, 79 (holding that, under the Anti-Kickback Statute, one factor cutting against "[o]vercriminalization" is the requirement that "a person must 'knowingly and willfully' provide prohibited remuneration to be

¹ The government's recent series of dismissals, now reaching three of seven counts and the corporate defendant, drastically reduced the total amount of payments at issue from approximately \$2.4 million to approximately a half-million dollars. As a result, defendants have explored and expect to identify an expert witness who can opine on value reflected in innovations among more than 50 patents held by SpineFrontier and affiliates, which the consulting program supported.

liable, which means she must have offered the payment with the intent to violate a known legal duty”). The same problems arise from *Pharmaceutical Coalition for Patient Access v. United States*, 126 F.4th 947, 962 (4th Cir. 2025), another civil case to which the government cites, which involved a challenge to HHS’s advisory opinion, again without remotely addressing evidentiary issues concerning a criminal defendant’s right to challenge express accusations in an Indictment or to attack the credibility of witnesses, or to rebut evidence of *mens rea* for the substantive offense or the corrupt intent of a conspiratorial agreement.

The criminal cases from other circuits on which the government relies also provide no help to its position. In *United States v. Patel*, 778 F.3d 607 (7th Cir. 2015), the court merely addressed the sufficiency of evidence to support a conviction, not the scope of admissible evidence with which to attack the credibility of witnesses or to rebut a finding of *mens rea* on the substantive offenses or conspiratorial intent to commit an unlawful act. *Id.* at 619 (focusing on whether a “reasonable factfinder could conclude that Patel ‘willfully and knowingly’ received a kickback”). In an unpublished decision on which the government relies that addressed a pertinent evidentiary ruling, the court in another of the government’s cited cases merely prevented a trial within a trial concerning medical necessity, while allowing evidence about helping patients and never asking any provider to do anything improper. *See United States v. Eggleston*, 823 F. App’x 340, 343 (6th Cir. 2020). In fact, the *Eggleston* court held that a defendant could resort to evidence of good treatment for “any other reason” than to argue medical necessity. *Id.* (“Eggleston’s cross-examinations of [government witnesses included ... h]er attorney asked about the treatment [patient] Hodge received and whether it helped her [and] Hodge confirmed that it did help,” and patient “Jones was likewise asked about his treatment and whether Eggleston ever asked him to do anything improper [and] Jones confirmed that Eggleston did not”) (citations to record omitted).

Simply put, the government has failed to justify the categorical preclusion of defense evidence and argument on which a jury could rely when determining the consulting program was not a sham, or with which a jury could assess credibility of government witnesses, or consider whether either defendant acted willfully or with conspiratorial intent to violate the law by inducing referrals rather than to innovate and improve patient care through the use of consultants. At the very least, the Court should await trial before considering a categorical preclusion of evidence and argument about impact on patients or the defendants' perception of such impact. Any contours of proof or jury instructions concerning these matters can be assessed best on an evidentiary record and with specific proffers of evidence at trial. Until then, there should be no categorical bar on the defendants' efforts to show reasons they believed in the proper purposes and benefits of the consulting program and show the lack of criminal or conspiratorial intent on the part of themselves or any other potential co-conspirator. The government's motion should be denied.

Conclusion

Based on the foregoing, defendants respectfully request that the Court deny the government's motion *in limine*.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that this document, filed on March 3, 2025, through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Joshua L. Solomon